during heat-treatment or hot-filling, **so that the dairy product can be produced combining the advantages of a hot-fill process (shelf-life extension by 1 to 3 months) and a cold-fill process (high quality product texture) without being forced to use an aseptic processing system**. Accordingly, an aqueous composition is provided which comprises whey protein concentrate (WPC), starch, a first hydrocolloid, and a second hydrocolloid, wherein the aqueous composition has been heated to a temperature in the range of 60 - 100°C for a period (holding time) of 1 to 120 minutes.

REMARKS

Applicants respectfully requests reconsideration of the above-identified application. Claims 1-8 and 14-18 are pending after entry of the present amendment.

Priority Document

As per requested by the Examiner, a certified copy of the priority document (Application No. 0019232.9 filed on 28/04/00) is enclosed.

Rejection Under 35 U.S.C.§101

Claims 9-13 have been rejected under 35 U.S.C. §101 as being non-statutory subject matter.

Although Applicants do not believe that simply using "use" in the claims makes them non-statutory subject matter, Applicants have chosen to cancel these claims thereby rendering this rejection moot.

Relevant Law For Rejection Under 35 U.S.C. §103

When analyzing an obviousness type rejection under 35 U.S.C. §103, the differences between the prior art and the claims at issue must be ascertained. *Graham v. John Deere Co.*, 148 USPQ 459 (Sup. Ct. 1966). The criterion for the determination of obviousness is whether the prior art would have suggested the invention to one of ordinary skill in the art, and that the invention would have a reasonable likelihood of success, viewed in light of the prior art. Both the suggestion

and the expectation of success must be founded in the prior art, and not in the Applicant's disclosure. *In re Dow Chemical Co.*, 5 USPQ.2d 1529 (Fed. Cir. 1988). The mere fact that the prior art can be modified does not make the modification obvious unless the prior art taught or suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984).

Moreover, the use of hindsight in rejecting claims under 35 U.S.C. §103(a) is not permissible. "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *W. L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 USPQ 303, 312-13. "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 5 USPQ.2d 1596, 1600 (Fed. Cir. 1988). This prohibition against hindsight reconstruction was reaffirmed in *In re Dembicizak*, 50 USPQ.2d 1614 (Fed. Cir. 1999):

> "Measuring a claimed invention against the standard established by section 103 require the oft-difficult but critical step of casting the mind back to the time of the invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then accepted wisdom in the field. Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one 'to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.'" *In re Dembicizak*, 50 USPQ.2d at 1617 (citations omitted) (emphasis added).

Rejection

Claims 18 and 14-18 have been rejected under 35 U.S.C. §103 as being obvious over Dunn et al. (U.S. Patent 5,614,243) in view of Asher et al. (U.S. Patent 5,251,777).

According to the Examiner, "Dunn et al disclose a starch based texturizing agent and process for preparing comprising a combination of starch, gums, and whey protein, where the starch is heated prior to mixing (see entire document) [and]

Asher et al discloses a texturizing agent and process of preparing comprising heating of the mixture and the use of whey protein concentrate." The Examiner concluded that it would have been obvious to a person of ordinary skill in the art, at the time the invention was made, to heat the entire mixture and use whey protein concentrate as taught by Asher et al in that of Dunn et al because heating may take place either before or after addition of all components and whey protein concentrate is a conventional source of whey protein."[1]

Applicants respectfully disagree. Applicants respectfully submit that the Examiner is effectively using hindsight reconstruction based on the inventor's specification to reject the claims. As the Examiner knows, and as detailed above, this is improper.

Dunn et al. is directed towards a texturing agent comprising an insoluble micro-particle (e.g., titanium dioxide), a gum (e.g., xanthan gum), and starch (e.g., pregelatinized starch) in the **form of a complex in which the insoluble micro-particles has been stabilized or entrapped therein**. Abstract. It is the titanium dioxide incorporated into a starch/gum matrix which results in the complex that has the texturizing properties. Col. 2, lines 39-57. The novel texturizing agents of Dunn et al. are prepared using a specific process:

> "The method for producing the novel texturizing agents generally involves: cooking the slurry under conditions of time, temperature, pressure, pH, ionic strength and shear sufficient to solubilize the starch by fully disrupting the starch granules while minimizing generation of objectionable side products which contribute off-flavor and off-color; filtering the solubilized starch to remove a substantial portion of non-starch components such as lipid and protein, preferably by treatment with diatomaceous earth and activated charcoal; adding a gum and optionally an insoluble microparticle (depending upon the final texturizing agent desired) under controlled conditions of temperature and shear; optionally homogenizing the filtrate; and cooling of the fully solubilized starch under controlled conditions of time, temperature and shear to yield a thixotropic gel. The retrograded texturizing agent can be dried to reduce the moisture content to provide a free-flowing powder. Alternatively the filtered starch solution is cooled to a temperature and for a

[1] The Examiner has not cited any specific portion of either reference to support here rejection. Should the Examiner maintain this rejection, Applicants respectfully request that the portions of the documents upon which the Examiner relies be pointed out.

period of time sufficient to allow partial precipitation of the starch, thereby resulting in a partially retrograded texturizing agent. In both instances, the texturizing agents can be used directly in food formulations. The dry powder may be used directly or can be rehydrated prior to use. Each of these steps are discussed in detail below.

"Specifically, the method involves preparing a starch slurry in an aqueous medium with a total high amylose starch content of from about 1 to about 30% (w/w) solids, preferably from about 5 to about 15% (w/w). For purposes of the present invention, "aqueous medium" is defined as water or a solution which is substantially water such as buffer, acid, base, salt, antioxidant, reducing agent, and/or chelating agent solutions or a blend of water with a miscible organic solvent, in an amount sufficient to inhibit oxidation of lipids present in the starch starting materials. It is preferred that the aqueous medium, such as water, be pretreated to remove any dissolved minerals. The starch may be hydrated at ambient temperature or after the aqueous medium has been heated.

"The resulting slurry is transferred into an evacuated reactor vessel equipped with appropriate stirring device for agitation during the cooking of the starch slurry. The starch slurry is subjected to controlled conditions of time, temperature, pressure, pH, ionic strength and shear, to fully disrupt the starch granules and solubilize the starch. For the purposes of the present invention, the term "solubilize" refers to the absence of any detectable particulate matter, especially partially disrupted starch granules, when viewed under 200 to 400 fold magnification using a standard light microscope. The rate of heating, time duration at the final cook temperature (i.e., the temperature above the gelatinization temperature of starch), and shear rate in the reactor vessel affect the properties of the final product.

"The slurry is typically heated from room temperature (approximately 22°C.) to from about 125°C. to about 150°C., with about 138°C. being preferred, under stirring over a time period which ranges from 40 to 120 minutes, preferably 60 minutes until starch granules are solubilized. Variations in initial temperature and rate of heating affect the properties of the final product even though the total time at 138°C. is essentially unchanged.

"The final temperature of 138°C. for cooking of the starch is preferred to produce texturizing agents that possess smooth mouthfeel, high opacity, and acceptable organoleptic properties. The complete disruption and solubilization of the starch is monitored by periodic sampling of small aliquots from the reactor over time and examination of the slurry under magnification (e.g., 200 to 400x) for presence or absence of starch granules. The heating step is considered complete when essentially all the starch granules have dissolved. The importance of the final temperature used in the present invention is illustrated by the following comparison. High amylose starch was heated to a maximum temperature in the reactor of 121°C. for 8 hours in the absence of shear. Even though the cooking process is carried out for a much longer time period than that of the present invention, this lower temperature does not allow for complete solubilization and disruption of the starch granules resulting in a product that contains relatively large particulates that

exhibit grittiness and poor mouthfeel when tasted directly. In contrast, the higher temperature used in the present process insures full disruption of the starch granules and solubilization of the high amylose starch which yield a much smoother product.

"Removal of oxygen from the slurry is important to produce a product with minimal off-color and off-flavor, as ascertained by visual and sensory perception. It is preferred that the dissolved oxygen content be less than 1 ppm to ensure that off-flavors resulting from oxidation are not perceived upon tasting. For example, this can be achieved by subjecting the slurry to a vacuum, sparging with an inert gas such as argon or nitrogen using either a vented vessel or closed vessel, or any combination of techniques effective for removal of dissolved gases especially oxygen from the slurry, such as oxygen scavengers. Deaerating step is carried out for a period of time necessary to insure removal of the bulk of the dissolved gases typically up to one hour, preferably, ten minutes. Other approaches to reduce off-flavors and off-colors may include, either alone or in combination, near complete removal of non-starch components from the starting material, the addition of antioxidants, reducing agents and or chelating agents to the slurry, or washing of the final product with aqueous or organic solvents, among other generally known methods.

"An alternative method of heating is to directly inject steam into the slurry, such as can be accomplished in a rapid heat-up device such as a jet cooker. Using a jet cooker or other rapid heat-up device, higher temperatures above the preferred range can be tolerated without affecting product properties if the contact time is sufficiently short. Generally, the temperature is raised up to about 160°C. and maintained at the elevated temperature for up to about ten minutes. Higher temperatures can be used for shorter time periods.

"Regulation of pH is also important to the texturizing properties of the product and the stability of the insoluble microparticle, such as titanium dioxide, in the starch complex. According to the methods of this invention, the typical pH of the slurry before and after cooking is in the range from about 3.0 to about 7.0, and preferably from about 4.3 to 4.7. The acidity of the slurry is controlled using appropriate food or cosmetic grade acidulants and alkali. The method of cooking will dictate the pH at which the starch is cooked. If a jet cooker is used, then the pH should be lower than that required for batch cooking.

"Upon complete disruption of the starch granules and solubilization of the starch, the starch solution is cooled to a temperature below boiling and above about 85°C. with 100°C. being preferred. Temperatures lower than about 85°C. will result in inefficient filtration as the starch retrogrades. Cooling can be accomplished by any suitable means such as heat exchanger, flash cooling or by running cooling water through the reactor jacket. The cooled starch solution is then transferred from the reactor vessel by expulsion under pressure, pumping, or other suitable method.

"The starch solution (at approximately 90°C.) is filtered to remove undissolved impurities, such as protein, fats and other compounds. Any

filtration device having metal sieves, ceramic filters or membranes, filter papers/cloths, filter pads or other filter media can be used. For example, plate and frame filter presses, cartridge, bag and pressure leaf filters can be used. It is desirable to preheat the filters and filtering device to the temperature of the slurry to be filtered prior to filtration. This will prevent premature retrogradation of the starch on the filter media and consequent blinding of the filter.

"The filtration step is preferably performed by filtering the solution through a secondary carbon-containing filter such as a filter fitted with activated charcoal impregnated pads or a filter fitted with a cartridge containing activated charcoal. In a preferred embodiment, a filter aid such as diatomaceous earth is typically added to the starch solution and stirred for about ten to about 120 minutes, with 60 minutes being preferred. The amount of diatomaceous earth used is generally from about 5% to about 20% by weight of the starch being purified, and is preferably about 10% by weight. The starch solution is then passed through a primary filter to remove the diatomaceous earth and then through the secondary filter containing the activated charcoal impregnated pads. Suitable carbon impregnated pads are available, for example, from Alsop Engineering Co., Kingston, N.Y. (S-51, grade 230).

"Alternatively, the filtration step is performed by treating the starch solution with activated charcoal. Activated charcoal is added to the reactor vessel for approximately from about 10 to about 120 minutes, with 60 minutes being preferred. Typically, the solution is simultaneously treated with a filtering aid such as diatomaceous earth, e.g. CELITE.RTM. (CELITE.RTM. Corp.). The amount of diatomaceous earth generally used is as described above. The starch solution containing suspended activated charcoal and diatomaceous earth is then filtered, as described above, to remove the charcoal and diatomaceous earth." Col. 4, line 14, through Col. 6, line 48.

This rather lengthy passage from Dunn et al. is quoted to specifically refute the Examiner's conclusion that, based on the teachings of Asher et al., that the heating in Dunn et al. "may take place either before or after the addition of all components." To reach this conclusion, the Examiner must effectively ignore the teachings in Dunn et al. regarding specific details as to how to incorporate titanium dioxide into the starch/gum matrix in order to form the complex that has the texturizing properties. In other words, the Examiner's conclusion requires that one of ordinary skill in the art simply ignore that Dunn et al. teaches that a specific process must be used to prepare their texturizing agent. There is no teaching or suggestion in Dunn et al. that a suitable complex (i.e., a complex in which the insoluble TiO_2 micro-particles has been stabilized or entrapped therein) could be

produced if the process if modified in the manner suggested by the Examiner in her rejection. This is mere speculation on the part of the Examiner. Moreover, Dunn et al. effectively teaches that the process should be carried out in the manner provided and thus specifically teaches away from the modified process as suggested by the Examiner.

Asher et al. is directed to a process for preparing a low or non-fat ice cream. The low or non-fat ice cream comprises about 5-15 percent milk solids non-fat, about 5-30 percent sweeteners, about 0.1-0.5 percent stabilizers and, at a temperature of about -12 to -10°C, about 45-60 percent frozen water in the form of ice crystals, at least about 40 percent of the ice crystals having a diameter of less than about 45 microns, and about 10-20 percent unfrozen water. The critical feature in Asher et al. appears to be the relative proportions of frozen and unfrozen water in the ice cream and the particle size of the ice crystals. Col. 1, lines 42-64.

Asher et al., like Dunn et al. above, provides a specific method for preparing their products. See, for example, col. 3, line 54, through col. 4, line 5. Once again, the Examiner's conclusion that heating in Dunn et al. "may take place either before or after the addition of all components" would seem to suggest that the person of ordinary skill in the art ignore the specific teachings of this reference.

Moreover, the Examiner has provided no motivation to combine the references. The Examiner has not provided any motivation for one of ordinary skill in the art to ignore the specific teachings of each reference in order to arrive at the Applicants' invention. Indeed, only hindsight using the Applicants' own teachings allows the Examiner to make this rejection.

Finally, the Examiner noted that in "the absence of unexpected results, it is not seen how the claimed invention differs from the teachings of the prior art." Applicants note that they have demonstrated above that the references as combined in the manner suggested by the Examiner do not lead the present invention.

Of course, the Examiner's last comment further implies that she does not believe the present invention provides unexpected results. Applicants respectfully disagree. As noted in the specification at the paragraph spanning pages 1 and 2, "the present invention . . . provide[s] a means for reducing or completely preventing

uncontrolled protein agglomeration in protein-containing dairy products during heat-treatment or hot-filling, so that a dairy product can be produced combining the advantages of a hot-fill process (shelf-life extension by 1 to 3 months) and a cold-fill process (high quality product texture) without being forced to use an aseptic processing system." And on page 5 it is notes that resulting food compositions containing the compositions of this invention exhibit "improved texture and, therefore, mouth-feel, as no uncontrolled or undesired protein agglomeration occurs during processing, e.g. heat-treatment or hot-filling." Applicants respectfully submit that these are surprising results and satisfy a need in the prior art.

Claims 1-8 and 14-18 are not obvious in light of the references of record. Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Applicants respectfully request that the Examiner allow pending claims 1-8 and 14-18 and pass this Application to issue.

If the Examiner believes that a telephonic or personal interview would be helpful to terminate any issues which may remain in the prosecution of the Application, the Examiner is requested to telephone Applicants' attorney at the telephone number set forth herein below.

The Commissioner is hereby authorized to charge any additional fees which may be required in the Application to Deposit Account No. 06-1135.

Respectfully submitted

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